

OCT - 3 2003

K032085

510(k) SUMMARY
NIDEK GREEN LASER PHOTOCOAGULATOR MODEL GYC-1000**1. SUBMITTER INFORMATION**

- A. Company Name: Nidek Incorporated
- B. Company Address: 47651 Westinghouse Drive.
Fremont, CA 94539-7474
- C. Company Phone: (510) 353-7719
Company Fax: (510) 226-5750
- D. Contact Person: Mr. Hiro Matsuzaki
Regulatory and QA Manager
Nidek Incorporated
- E. Date Summary Prepared: October 1, 2003

2. DEVICE IDENTIFICATION

- A. Classification Name: Ophthalmic Laser, and Powered Surgical Laser Instrument
- B. Trade/Proprietary Name: Nidek Green Laser Photocoagulator
Model GYC-1000
- C. Device Classification: Class II (per 21 CFR 886.4390 and 878.4810)
- D. Product Code: HQF and GEX

3. SUBSTANTIAL EQUIVALENCE

The Nidek Green Laser Photocoagulator Model GYC-1000 is of comparable type and is substantially equivalent to the following predicate device:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Nidek Laser Photocoagulator Model GYC-1500/2000	Nidek Co. Ltd. Japan	K980547	May 13, 1998

The fundamental technical characteristics and device specifications of the Nidek Green Laser Photocoagulator Model GYC-1000 are the same as those of the predicate device. The Model GYC-1000 and the predicate device are frequency doubled solid-state lasers with a wavelength of 532 nm. The Model GYC-1000 and the predicate device use a variety of delivery systems, including slit lamps, indirect ophthalmoscopes, endoprobes, and Nd:YAG lasers to deliver the laser beam. The Model GYC-1000 and the predicate device are indicated for use in macular and retinal photocoagulation, and glaucoma procedures such as iridotomy and trabeculoplasty.

4. DEVICE DESCRIPTION

The Nidek Green Laser Photocoagulator Model GYC-1000 is a frequency doubled diode pumped solid state (DPSS) laser ophthalmic photocoagulation system that produces a 532 nm (green) wavelength light as the treatment beam. The Model GYC-1000 uses a diode laser (red) with a wavelength of 635 nm as the aiming beam. The green laser beam is aligned with the red aiming laser beam in the optical system inside the unit and gathers them in a fiber-optic cable. The laser beam is led to the delivery unit via the fiber-optic cable, shaped into the specified spot size in the optical system, and emitted to the affected area (the emission areas of both the therapeutic laser beam and the aiming beam are the same).

The Model GYC-1000 can be used to coagulate the target tissue efficiently and safely, and the system can be applied to transpupillary photocoagulation procedures using a slit-lamp or indirect ophthalmoscope and intraocular photocoagulation procedures using an endophotocoagulation probe. The Model GYC-1000 is a smaller, modified version of the Models GYC-1500 and GYC-2000, which were the subject of premarket notification number K980547.

A protective filter may be attached to each delivery unit in the observation optical path so that the operator's eye can be protected from the laser beam if it is reflected

from a patient's eye or contact lens during laser emission. The Model GYC-1000 has a number of delivery units available for use in a variety of ophthalmic procedures:

- Endophotocoagulation Delivery Unit
- NIDEK Slit-Lamp Delivery Unit
- ZEISS Slit-Lamp Attachable Delivery Unit
- HAAG Attachable Slit-Lamp Delivery Unit
- Binocular Indirect Ophthalmoscope Delivery Unit
- Combination Delivery Unit for Nidek Nd:YAG laser

5. INDICATIONS FOR USE

The Nidek Green Laser Photocoagulator Model GYC-1000 is indicated for use in ophthalmic surgical procedures, including retinal and macular photocoagulation, iridotomy and trabeculoplasty.

6. TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Nidek Green Laser Photocoagulator Model GYC-1000 and the predicate device has been performed, and the results are summarized in the table below. The results of this comparison demonstrate that the Nidek Green Laser Photocoagulator Model GYC-1000 has the same basic technological characteristics as the predicate device and is equivalent to the marketed predicate device. The differences between the Nidek Green Laser Photocoagulator Model GYC-1000 and the predicate device are insignificant and do not affect the safety or effectiveness of the device.

PREDICATE DEVICE COMPARISON TABLE		
	Nidek Model GYC-1000	Nidek GYC-1500/2000 K980547 (Predicate Device)
Treatment Laser		
Laser Type	Laser diode pumped, frequency doubled Nd:YAG solid state laser	Model GYC-1500: Arclamp (Krypton) pumped, frequency doubled Nd:YAG solid state laser Model GYC-2000: Laser diode pumped, frequency doubled Nd:YAG solid state laser
Wavelength	532 nm	532 nm
Output	Continuous Wave	Continuous Wave
Power Output	50 to 1700mW (50 to 500mW in 10mW increments, 500 to 1700mW in 50mW increments)	50 to 1500mW in 10mW increments (Model I) or 50 to 2000mW in 10mW increments (Model II)
Exposure Time	0.01 to 0.10 sec. in 0.01 sec. increments 0.10 to 0.50 sec. in 0.05 sec. increments 0.50 to 1.00 sec. in 0.10 sec. increments 1.00 to 3.00 sec. in 1.00 sec. increments	0.02 to 3.00 sec.
Repetition Mode	Interval time 1.0 to 0.1 sec. in 0.1 sec. increments	1.0, 0.6, 0.4 and 0.2 sec.
Cooling Method	Air cooled	Internal water cooling system
Microprocessor	Two CPU's: Master CPU for controlling the device, and Sub CPU for monitoring the Master CPU	One CPU
Aiming Laser		
Type	Diode Laser	Diode Laser
Wavelength	635 nm (red)	633 nm (red)
Output Type	Continuous Wave	Continuous Wave
Power Output	02 to 0.4mW	0.2 to 0.8mW
Accessories		
Endophotocoagulation Delivery Unit	Straight and angled probes, which are single-use disposable	Straight and angled probes, which are single-use disposable
Slit Lamp Delivery Unit	Nidek SL-1600 Type	Nidek SL-1600 Type
Slit Lamp Adaptors	• Zeiss Type	• Zeiss Type

PREDICATE DEVICE COMPARISON TABLE		
	Nidek Model GYC-1000	Nidek GYC-1500/2000 K980547 (Predicate Device)
	<ul style="list-style-type: none"> • Haag Streit Type 	<ul style="list-style-type: none"> • Haag Streit Type
Binocular Indirect Ophthalmoscope (B.I.O.) Delivery Unit	Heine Omega 180 Type	Heine Omega 180 Type
Combination Delivery Unit	For use with Nidek Nd:YAG lasers	For use with Nidek Nd:YAG lasers
Spot Size at Target	<ul style="list-style-type: none"> • 50 to 500 μm (parfocal) for Combination Unit and Slit Lamp Units • 180 to 520 μm for B.I.O. • 400 μm for Endo probes 	<ul style="list-style-type: none"> • 50 to 500 μm (parfocal) for Combination Unit and Slit Lamp Units • 180 to 520 μm for B.I.O. • 400 μm for Endo probes
Operating Microscope Filters	<ul style="list-style-type: none"> • Zeiss • Möeller Wedel • Topcon • Wild 	<ul style="list-style-type: none"> • Zeiss • Möeller Wedel • Topcon • Wild
Power Requirements	90-264 VAC, 50/60 Hz, 200 VA	100/120/230 VAC, 50/60 Hz, 1500 VA (continuous)

7. PERFORMANCE DATA

System and component testing was completed based on product specifications and hazard effects determined from the risk analysis. The following testing was performed on the Nidek Green Laser Photocoagulator Model GYC-1000 to demonstrate that it meets all specified requirements and is equivalent to the predicate device:

A. Electrical Safety Testing & Electromagnetic Compatibility

The Nidek Green Laser Photocoagulator Model GYC-1000 was tested in accordance with EN 60601-1 and EN 60601-1-2, and was found to meet all requirements of both standards.

B. Programmable Electrical Medical Systems

The Nidek Green Laser Photocoagulator Model GYC-1000 was tested in accordance with EN 60601-1-4 and was found to meet all requirements of the standard.

C. Requirements For The Safety Of Diagnostic And Therapeutic Laser Equipment

The Nidek Green Laser Photocoagulator Model GYC-1000 was tested in accordance with IEC 60601-2-22, JIS T1204, and JIS C6802, and was found to meet all requirements of the standards.

8. CONCLUSIONS

Nidek Incorporated has demonstrated through its evaluation of the Nidek Green Laser Photocoagulator Model GYC-1000 that the device is equivalent to the predicate device with respect to intended use, technological characteristics, and safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 2003

Mr. Hiro Matsuzaki
Regulatory and QA Manager
Nidek Incorporated
47651 Westinghouse Drive
Fremont, CA 94539-7474

Re: K032085

Trade/Device Name: Nidek Green Laser Photocoagulator Model GYC-1000

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Regulatory Class: II

Product Code: GEX

Dated: July 1, 2003

Received: July 7, 2003

Dear Mr. Matsuzaki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

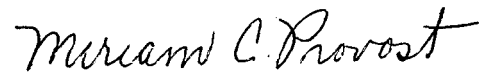
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Hiro Matsuzaki

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE510(k) Number: K032085 (To Be Assigned By FDA)

Device Trade Name: Nidek Green Laser Photocoagulator Model GYC-1000

Indications For Use: The Nidek Green Laser Photocoagulator Model GYC-1000 is indicated for use in ophthalmic surgical procedures, including retinal and macular photocoagulation, iridotomy and trabeculoplasty.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

OR

Over-The-Counter Use _____

(Per 21 CFR 801.109)

Miriam C Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032085